DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

October 8, 2014

A&D Engineering, Inc.
c/o Mr. Jerry Wang
Director of Engineering
1756 Automation Parkway
San Jose, CA 95131

Re: K141201
Trade/Device Name: A&D Medical UA-767F and UA-767FAC Digital Blood Pressure Monitors
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system.
Regulatory Class: Class II
Product Code: DXN
Dated: September 5, 2014
Received: September 8, 2014

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141201

Device Name
A&D Medical UA-767F & UA-767FAC Digital Blood Pressure Monitors

Indications for Use *(Describe)*
The UA-767F and UA-767FAC are designed to be used by users who are older than twelve (12) years at home or clinics to monitor their blood pressure (systolic and diastolic) and pulse rate. The arm circumference range shall be between 8.7 inches (22.0 cm) and 17.7 inches (45.0 cm).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K141201 510(k) Summary

This summary of 510(k) safety and effective information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1. Date Prepared

September 30, 2014

2. Submitter's Information

A&D Engineering, Inc.
Mr. Jerry Wang
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Tel: 408-518-5113
Fax: 408-635-2313
Email: jwang@andonline.com

3. Device Information

Proprietary Name:	A&D Medical UA-767F and UA-767FAC Digital Blood Pressure Monitors
Common/Usual Name:	Blood Pressure Monitor
Classification name:	Non-invasive blood pressure measurement System 21 CFR 870-1130, Class II, 74DXN.

4. Predicate Devices

A&D Model UA-767PBT Digital Blood Pressure Monitor with 510(k) number K043217
A&D Model UA-1000 Family Digital Blood Pressure Monitors with 510(k) number K111686
Predicate devices are designed and manufactured by the same company and facilities as the modified devices UA-767F and UA-767FAC.

5. Device Description – Technological and Operational Characteristics

UA-767F and UA-767FAC have the same design except UA-767FAC having an AC plug for an external AC adapter connection. Both devices use an inflatable cuff which is wrapped around the patient's upper arm. After the user pushes the "START" button, the cuff is inflated automatically by an internal pump of UA-767F and UA-767FAC. The systolic and diastolic blood pressures are determined by oscillometric method. The deflation rate is controlled by the internal exhaust valve. There is a quick exhaust mechanism so that the cuff pressure can be completely released urgently. There is a maximum pressure safety setting at 300mmHg. UA-767F and UA-767FAC will not inflate the cuff higher than 300mmHg. UA-767F and UA-767FAC will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and stored in the device memory. The cuff is also deflated automatically to 0 mmHg at the same time.

6. Indications of Use

The UA-767F and UA-767FAC are designed to be used by users who are older than twelve (12) years at home or clinics to monitor their blood pressure (systolic and diastolic) and pulse rate. The arm circumference range shall be between 8.7 inches (22.0 cm) to 17.7 inches (45.0 cm).

This indication for use of A&D Medial UA-767F and UA-767FAC as described in the labeling and FDA IFU form 3881 are the same as their predicated devices, UA-1000 family and UA-767PBT.

7. Summary of Substantial Equivalence

Modifications made from the predicate devices:

- Change the plastic molds so UA-767F & UA-767FAC have a different appearance
- Modify memory size and add %IHB feature in memory average display. Remove AM / PM function.
- Enable up to four users to share the same device.
- Replace the static capacity type pressure sensor to semiconductor pressure sensor.
- Remove the following functions from UA-1000 family – Voice, Tricheck, and AM/PM measurement average.
- Remove the Bluetooth wireless communication from UA-767PBT.
- Add a new wide range cuff, model UA-420, to cover arm size 22 to 42 cm. The predicate UA-290 (23 to 37 cm) and UA-291 (31 to 45 cm) cuffs remain working.

Product Specification Comparison

Parameter	**Predicate Devices (UA-1000 family & UA-767PBT)**	**Modified Devices (UA-767F & UA-767FAC)**
Power source	4 AA size batteries and AC adaptor as an option	No Change – the same
Battery Life	4 months with daily measurement	No change – the same
Measurement Method	Oscillometric Method	No change – the same
Measurement Range	BP : 20 to 280 mmHg Pulse : 30 to 200 beats/min	BP: 0 -299 mmHg Pulse: 30 to 200 beats/min
Accuracy	BP : +/- 3mmHg or +/- 2% of measured value, whichever is greater Pulse : +/- 5 % (pulse)	BP : +/- 3mmHg Pulse : +/- 5 %
Pressurization Source	Automatic internal pump	No change – the same
Cuff Deflation Method	UA-767PBT – Standard exhaust valve UA-1000 family – Constant speed electrical controlled exhaust valve (ECEV method)	No change – the same as UA-767PBT
Display Type	Liquid crystal display	No change – the same

Cuff Attachment Method	By plastic hose connected to monitor	No change – the same
IHB (Irregular Heartbeats Detection)	More than +/-25% to the mean interval of all pulse intervals	No change – the same
Operating Environment	50^0F (10^0C) to 104^0F (40^0C) 30 %RH to 85% RH	50^0F (10^0C) to 104^0F (40^0C) 15 %RH to 85% RH
Storage Environment	14^0F (-20^0C) to 140^0F (60^0C) 10 %RH to 95% RH	No change – the same
Pressure Indicator	UA-1000 family (Yes) under USA JUC VII guideline	No change – the same
Number of User	One	Up to four
Data Memory Size with Time & Date	90 memories for UA-1000 family 40 memories for UA-767PBT	Change to 60 memories for each user with %IHB feature
Pressure Sensor design	Static electricity capacity type	Semiconductor type
Dimensions in mm	UA-767PBT: 163.7 x 111 x 66.7 UA-1000 Family: 140 x 60 x 105	96 (W) x 68 (H) x 130 (D)
Weight	UA-1010–265g UA-1020–285g UA-1030T–300g without batteries	240g without batteries
Cuff Design	UA-767PBT – D-ring cuffs UA-1000 family – U-shape cuffs	No change – the same as UA-767PBT
Arm Size	UA-289 small cuff : 16 to 24 cm UA-290 medium cuff : 23 to 37 cm UA-291 large cuff : 31 to 45 cm	No change – UA-290 and UA-291. New cuff model – UA-420 : 22 to 42cm.
Clock (Time/Date)	Yes for UA-1020 and UA-1030T	No change – the same
Talking	Yes – UA-1030T, No - others	Removed
AM/PM	Yes – UA-1020 & UA-1030T	Removed
Wireless Radio Connectivity	UA-1000 family (No), UA-767PBT (Yes)	Removed
Personal PC Analysis Software	UA-1000 family (No), UA-767PBT (Yes)	Removed

Key Features Comparison

Parameter	**Predicate Devices (UA-1000 family & UA-767PBT)**	**Modified Devices (UA-767F & UA-767FAC)**
Field service	Not allowed	No Change – the same
Automatic zero at "START"	Yes	No Change – the same
Manual zero adjustment	Not allowed	No Change – the same
Calibration	Not allowed in the field	No Change – the same
Sterilization	Not needed	No Change – the same

8. Discussion of standards used in the design verification and design validation

We conducted design verification and design validation activities based on the comparison of the UA-767F and UA-767FAC with the predicate devices. Based on the changes, we conducted the appropriated test methodology and pass/fail criteria. After the tests were conducted, the test records were collected in the design history file (DHF).

A&D Medical follows FDA regulation and international standards in our medical device development and manufacturing processes. The following standards were used to demonstrate compliance to FDA recognized consensus standards for the UA-767F and UA-767FAC devices.

- ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.
- AAMI/ANSI 60601-1:2006 Medical electrical equipment. General requirements for basic safety and essential performance
- AAMI/ANSI/IEC 60601-1-2:2007 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
- AAMI/ANSI/ISO 14971:2012 Medical devices. Application of risk management to medical devices

There is no new material involved from the predicate devices to UA-767F and UA-767FAC. So, there is no need to conduct any biocompatibility tests.

UA-767F and UA-767FAC met all applicable requirements of the standards. None of the test demonstrated that the UA-767F and UA-767FAC bring new issues of safety and effectiveness.

Substantial Equivalence Conclusion:

UA-767F and UA-767FAC Digital blood pressure monitors have the following similarities to the predicate devices, UA-1000 family and UA-767PBT digital blood pressure monitors, which previously received the 510(k) clearance.

Comparison Area	**Predicate Devices UA-767PBT & UA-1000**	**Subject Devices (UA-767F & UA-767FAC**
Indication of Use	Measure blood pressure (systolic and diastolic) and pulse rate.	Measure blood pressure (systolic and diastolic) and pulse rate. **(identical to both)**
Intended Use	Measure systolic, diastolic and pulse rate for adults at home and clinics.	Measure systolic, diastolic and pulse rate for adults at home and clinics. **(identical to both)**

Measurement Method	Oscillometric Method	Oscillometric Method **(identical to both)**
Inflation Method	Automatic internal pump	Automatic internal pump **(identical to both)**
Deflation Method	Standard exhaust valve	Standard exhaust valve **(identical to UA-767PBT)**
Materials	PVC, nylon, metal.	PVC, nylon, metal **(identical to both)**
Energy source	AA batteries with AC adapter as an option.	AA batteries with AC adapter as an option. **(identical to both)**

As a conclusion, the intended use of the modified device, UA-767F and UA-767FAC as described in its labeling, has not changed as a result of the modifications. The fundamental scientific technology of the modified device, UA-767F and UA-767FAC, has not changed, either. The results of the previous activities demonstrate that the A&D Medical UA-767F and UA-767FAC Digital Blood Pressure Monitors are as safe, as effective, and performs as well as or better than the predicate devices.